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APPEAL BRIEF

Applicant : Stephen T. Dybing

App. No : 10/646,852

Filed : August 22, 2003

For : METHOD FOR PRODUCING A FOOD
PRODUCT FROM A
CONCENTRATED PROTEIN

Examiner : Leslie A. Wong

Art Unit : 1794

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the Notice of Appeal filed December 21, 2009, Applicant submits this Appeal Brief.

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I. REAL PARTY IN INTEREST

The real party in interest in the present application is Fonterra Co-Operative Group Ltd., the assignee of record by virtue of the assignment recorded at Reel 014483 Frame 0043.

II. RELATED APPEALS AND INTERFERENCES

Applicants do not know of any prior appeals, pending appeals, judicial proceedings, or interferences that may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 2-8, 10-13, 16-22, 27, and 33-45 are currently pending. Claims 1, 9, 14, 15, 23-26, and 28-32 were canceled. Claims 2-8, 10-13, 16-22, 27, and 33-45 were finally rejected by the Examiner, and are the subject of this appeal. A copy of the appealed claims is attached as the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Amendments filed on May 20, 2009 were entered. No claims have been amended subsequent to the Final Office Action dated August 20, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present application relates generally to methods for making food products from concentrated protein. Each independent claim that is currently under consideration is summarized below, with reference to the originally-filed specification and drawings as required by 37 C.F.R. § 41.37(c)(1)(v). These citations are provided to enable the Board to more quickly determine where the claimed subject matter is supported in the application, and are not intended to limit the claims.

Independent Claim 33 is directed to a method of making cheese. The method comprises mixing nonfat dry milk comprising milk proteins with water to form reconstituted skim milk, wherein the water comprises a monovalent salt prior to mixing. Paragraphs [0014], [0022], [0041], [0053], [0073], and [0083]. The method further comprises combining the reconstituted

skim milk with concentrated milk fat. Paragraphs [0063] and [0089]; Figure 1. The method further comprises homogenizing the combined milk and fat to produce cream. Figure 1; paragraphs [0017], [0061], [0068], and [0089]. The method further comprises diluting the cream with milk to produce standardized milk. Figure 1; paragraphs [0063] and [0088]-[0092]. The method further comprises using the standardized milk to make cheese. Figure 1, paragraphs [0088]-[0092].

Independent Claim 38 is directed to a method of producing a food product from concentrated protein. The method comprises mixing the concentrated protein with water to form a hydrated protein solution. Figure 1, paragraphs [0016], [0044], [0047]. The method further comprises adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein, wherein the concentrated protein comprises concentrated milk protein. Figure 1, paragraphs [0022], [0035], [0044], [0048], and [0053]. The method further comprises mixing the hydrated protein solution with a concentrated fat to form a first food product. Figure 1 and paragraphs [0017], [0059], and [0060].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection presented for review are as follows. Appellants have elected to separately present arguments for selected dependent claims.

- A. Claims 2-8, 10-13, 16-22, and 38-45 stand rejected under 35 U.S.C. § 102(e) as anticipated by WO 02/096208 to Carr (hereinafter "Carr").**
- B. Claims 2-8, 10-13, 16-22, and 38-45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carr.**
- C. Claims 33-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carr in view of U.S. Patent No. 6,358,551 to Sadowsky (hereinafter "Sadowsky").**
- D. Claim 27 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Carr and Sadowsky.**

- E. Claims 39-45 stand rejected under 35 U.S.C. § 102(e) as anticipated by Carr.**
- F. Claims 39-45 stand rejected under 35 U.S.C. § 103 as unpatentable over Carr.**
- G. Claims 43-45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carr and Sadowsky.**

VII. ARGUMENT

1. Summary of the Teachings of the Cited References

a. Summary of PCT Patent Publication WO 02/096208 to Carr

Carr discloses enhanced-solubility milk protein concentrate (MPC) containing at least one monovalent salt. Page 2, lines 15-18. Carr discloses that dried MPC and milk protein isolate (MPI) can have poor solubility and that solubility can decrease with storage. Page 1, lines 28-32. Carr discloses that the solubility of the MPC can be enhanced by adding a monovalent or divalent salt to milk and subsequently drying to form MPC. Page 3, lines 6-8.

Carr discloses various examples of modifying MPC by adding salt prior to drying. In Example 3, Carr discloses that the addition of salt is necessary prior to drying in order to increase the solubility of the MPC. Page 10, line 28 to page 11, line 2.

In Example 9, Carr discloses using samples of 85% milk protein for cheese making. Page 12, line 13 to page 13, line 2. In Example 9, fresh cream is added to skim milk and separated into separate batches. Page 12, lines 15-20. Different dried MPC compositions were added to each batch of skim milk and cream. Page 12, lines 20-25. The powders were dispersed in the milk and a standard cheddar process was used for cheese manufacture. Page 12, line 31.

Thus, Carr is concerned with improving the solubility of MPC by adding salt to milk and then drying to form MPC. Carr does not mention and is not concerned with enhancing the emulsification properties of the MPC.

b. Summary of U.S. Patent No. 6,358,551 to Sadowsky

Sadowsky discloses a method for incorporating concentrated milkfat into milk to form a concentrated milkfat/milk blend or substrate which can be used in the preparation of natural cheese without the use of stabilizers. Col. 2, lines 2-8.

Sadowsky discloses that “[g]enerally, the amount of concentrated milkfat added to the first portion of the reduced-fat raw milk is about 4 to about 10 percent.” Col. 5, ll. 43-45. Example 1 of Sadowsky discloses forming a slurry with 8.4% fat. Example 2 of Sadowsky discloses forming a slurry with 3.9% fat.

2. Arguments Corresponding to Grounds of Rejections

a. Claims 2-8, 10-13, 16-22, and 38 are not anticipated by Carr

i. Legal standard

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

The Federal Circuit recently clarified the law of anticipation, stating that “[w]e thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed *but also all of the limitations arranged or combined in the same way as recited in the claim*, it cannot be said to prove prior invention of the thing claimed and thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIn, Inc., v. Verisign, Inc.*, No. 2007-1565, slip opinion at pg. 17-18 (Fed. Cir. 2008).

Applicants also note that “[i]nherency, however, may not be established by probabilities or possibilities. The fact that a given thing *may* result from a given set of circumstances is not sufficient.” *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). *See also Tintec Industries, Inc. v. Top-USA Corp.*, 63 U.S.P.Q.2d 1597, 1599 (Fed. Cir. 2002). When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably

support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added).

ii. Carr fails to anticipate Claims 2-8, 10-13, 16-22, and 38

Claim 38 is independent and Claims 2-8, 10-13, and 16-22 depend directly or indirectly from Claim 38. Claim 38 is directed to a method comprising adjusting the ionic composition of a hydrated protein solution to enhance its ability to emulsify fat in water. In rejecting Claim 38 the Examiner found that “Carr teaches a process for preparing an enhanced-solubility milk protein concentrate comprising providing a milk protein concentrate in aqueous solution/suspension and adding at least one monovalent salt (e.g. sodium chloride) in an amount that confers enhanced solubility on the product”. Office Action dated August 20, 2009 at page 3. The Examiner further found “Carr teaches the use of the prepared milk protein concentrate in the preparation of cheese wherein protein and concentrated fat (i.e. cream) are added to the enhanced solubility milk protein concentrate (see Example 9), wherein the cheese is then prepared by a conventional process”. *Id.* The Examiner further found that “[a]n increase in the emulsion capacity and stability would be no more than inherent and/or obvious to that of Carr as the same components and process steps are used.” *Id.*

First, Applicant submits that Carr does not disclose the steps or order of steps recited in independent Claim 38. Carr fails to disclose “adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water”. Rather, Carr discloses adding monovalent salt to milk protein in solution and then drying to form an MPC. Carr also doesn’t teach “mixing the hydrated protein solution with a concentrated fat to form a first food product”. In Carr, the Examiner is suggesting that the salt is added to a hydrated protein solution. However, the solution is subsequently dried. Thus, if the Examiner’s construction is adopted, Carr does not mix the hydrated protein solution to which salt has been added with fat. Thus, Carr cannot anticipate Claim 38 even if Applicant does not exclude some steps used in Carr.

Further, Carr does not teach adjusting the ionic composition to enhance the ability to emulsify fat in water. There is no teaching of doing so in Carr, which is only concerned with *solubility of dried MPC* and making *low fat* products.

In responding to the Applicant's prior arguments that Carr does not anticipate independent Claim 38 because it does not teach specific steps in the claims, the Examiner found that "Applicant merely claims 'enhance its ability to emulsify fat.' Applicant does not specifically claim an enhanced emulsion." (*Id.* at page 5.)

With regards to the Examiner's finding that an enhanced emulsion is not claimed, Applicant points out that the pending claims are method claims and not product claims and thus an emulsion itself is not claimed. However, enhancing the ability of the protein solution to emulsify fat is a meaningful physical change that is an explicit part of the claimed process and must be given patentable weight. Claim 38 clearly recites "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein".

The Examiner further found that "Applicant does not exclude the additional steps of Carr" (*Id.* at page 4). However, it is irrelevant that the claims do not exclude any "additional steps of Carr" because Carr fails to disclose the steps recited in Claim 38.

Applicant also continues to disagree with the Examiner's characterization of Carr. Again, the Examiner has said that an increase in emulsion capability and stability would be inherent. Example 9 of Carr, relied on by the Examiner, discloses adding fresh cream to fresh skim milk and subsequently adding various compositions of MPC85 to the mixture of fresh cream and fresh skim milk. Carr, page 9, ll. 13-25. Carr fails to disclose adding salt to the mixture. Thus, Carr fails to disclose adjusting the ionic composition of the hydrated protein solution. Carr is concerned with preparing a dried enhanced-solubility MPC. Carr discloses that "[t]he term 'enhanced solubility' refers to the property of a product which on reconstitution into a 5% w/v solution provides less sediment on centrifugation for 10 minutes at 700g relative to the corresponding product without salt treatment." Carr, page 2, lines 33-35. There is no disclosure in Carr regarding emulsification properties. Claim 38 itself clearly defines the enhanced ability to emulsify fat in water as increased emulsion capacity and increased emulsion stability in comparison to untreated protein. This is not the same as enhanced solubility.

The Examiner has only provided a conclusory statement which clearly does not meet the required burden for showing inherency. When relying upon the theory of inherency, the

Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added). The Examiner has failed to provide any facts or technical reasoning to support her finding of inherency. Even if the process of Carr disclosed adding salt to the hydrated solution that is mixed with fat, which it does not, there is no reason to believe that enhanced emulsification would be inherent.

Carr focuses on *enhancing the solubility* of dried MPC. Enhanced solubility and enhanced emulsification are *not* synonymous. Briefly, the highly polar nature of water molecules prevents water from effectively interacting with the distinctly non-polar fat or oil molecules. The polarity differences therefore prevent fats/oils from dissolving in water, and force water and fat/oil to separate into distinct, independent phases, unless stabilized as emulsions by emulsifiers. Emulsifiers are typically molecules with two distinctly different sections:

- A. a highly polar section that interacts with the highly polar water molecules, and
- B. a highly non-polar section that interacts with the non-polar fat/oil

The shape or conformation of the molecule allows both sections to freely interact with components of the respective polarity: i.e. the highly polar section must freely interact with water, while the non-polar section simultaneously must freely interact with the fat/oil phase. Therefore, effective emulsifiers typically have both the correct molecular structure (i.e. both the separate polar and non-polar sections) and the correct conformation (i.e. the correct shape positioning the separate sections so that these sections simultaneously and freely interact with the respective components).

Increasing the solubility of any particular protein does not inherently enhance the ability of that protein to emulsify fat. Indeed, enhancing the solubility of most proteins may proportionally decrease the ability of those proteins to emulsify fat. The solubility of a protein depends upon the protein assuming a conformation that maximizes the exposure of the polar amino acid groups in the protein's primary structure to water. These conformations must simultaneously minimize the surface exposure of the non-polar amino acids, because the inability of non-polar amino acids to interact with water proportionally reduces solubility. Therefore any protein conformation maximizing solubility must fold the non-polar amino acids deep into the

protein interior, essentially masking the inherent incompatibility of polar and non-polar compounds. Positioning the non-polar amino acids within the protein interior renders these sections incapable of simultaneously interacting with fat. Unable to interact with the fat, these proteins *cannot* effectively act as emulsifiers. Such conformations proportionally increase the solubility of the protein, while simultaneously reducing the ability of that protein to effectively emulsify fat.

Again, the Examiner has provided no basis for concluding that emulsification is inherent. Therefore, Carr fails to inherently or explicitly disclose “adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein”. Carr also fails to disclose explicitly or inherently “mixing the hydrated protein solution with a concentrated fat to form a first food product” as recited in Claim 38.

Accordingly, because Carr does not teach, inherently or explicitly, each of the elements of the claims, Applicant respectfully request withdrawal of the anticipation rejection of Claims 2-8, 10-13, 16-22, and 38 for at least this reason.

b. Claims 2-8, 10-13, 16-22, and 38 are patentable over Carr.

i. Legal Standard for Obviousness

It is well settled that the Examiner “bears the initial burden of presenting a *prima facie* case of unpatentability...” *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); (“the need to demonstrate the presence of all claim limitations in the prior art was not obviated [by KSR]”, *Abbott Labs. v. Sandoz, Inc.*, 2007 WL 1549498, *4 (N.D. Ill. May 24, 2007)); *see also M.P.E.P.* § 2143.03. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir.

1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also* *M.P.E.P.* § 2143.02. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F.3d 977, 988 (C.A.Fed.2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1740-1741 (2007).

ii. Carr is not prior art under 35 U.S.C. § 103(c) to at least Claims 38, 2-8, 10-13, 16, and 27.

The Examiner also rejected Claims 38, 2-8, 10-13, 16, and 27 under 35 U.S.C. § 103 as unpatentable in view of Carr. In the Office Action the Examiner conclusively stated that “It is noted that provisional application 60/405791 does not correspond to the current application. Specifically, 60/405791 is not directed to the addition of a monovalent salt. Applicant is not entitled to the priority date of the provisional application.” Office Action dated August 20, 2009 at page 2. Applicant respectfully disagrees with this conclusory statement and notes that the Examiner did not provide a claim by claim analysis of the priority. Even assuming *arguendo* that

the provisional application does not disclose addition of a monovalent salt, at least Claims 38, 2-8, 10-13, 16, and 27 do not require a monovalent salt and are clearly supported by the provisional and thus entitled to priority.

Applicant notes that the Examiner did not respond to the Applicant's repeated arguments that Carr is an improper reference under 35 U.S.C. § 103 for claims entitled to the priority date of provisional application 60/405791. Claim 38 is clearly supported in the provisional application. *See* paragraphs [0002], [0006], [0007], [0014], [0015], [0016], [0018], [0019], [0021], and [0022] and Figure 1 of Provisional patent application serial number 60/405,791. Further, Claims 2-8, 10-13, 16, and 27 do not recite monovalent salt and are also clearly supported by the provisional patent application. Support for Claims 2-8, 10-13, 16, and 27 can be found throughout the provisional application as filed, for example, in Figure 1, the claims, and paragraphs [0002], [0006], [0007], [0012], [0014], [0015], [0016], [0018], [0019], [0021], and [0022].

Carr is cited as a prior art reference under 35 U.S.C. § 102(e) for claims entitled to the priority of the provisional application. As discussed above, these claims include at least Claims 38, 2-8, 10-13, 16, and 27. 35 U.S.C. § 103(c)(1) states:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103(c)(1).

Carr and the present application were both owned or under a common obligation of assignment to Fonterra Co-Operative Group Ltd. at the time the claimed inventions were made. The Assignment of the present application to Fonterra Co-Operative Group Ltd. is recorded at Reel 014483, Frame 0043. The Applicant for Carr is the New Zealand Dairy Board. In October of 2001 Fonterra Co-Operative Group Ltd. was formed by the merger of the New Zealand Dairy Board with the New Zealand Dairy Group and Kiwi Co-operative Dairies. *See* the attached history of Fonterra Co-Operative Group Ltd, included in the Appendix, which can be found at

<http://www.fonterra.com/wps/wcm/connect/fonterra.com/fonterra.com/our+business/fonterra+at+a+glance/about+us/our+history>.

Therefore, Applicant respectfully submits that Carr is not a proper reference under 35 U.S.C. § 103 to at least Claims 38, 2-8, 10-13, 16, and 27. Accordingly, Applicant respectfully requests withdrawal of the rejection of these claims under 35 U.S.C. § 103 for at least this reason.

iii. Carr fails to render Claims 2-8, 10-13, 16-22, and 38 obvious

Even if Carr was a proper prior art reference, as discussed above, Carr fails to suggest or make obvious all of the features of Claim 38 explicitly or inherently. (“the need to demonstrate the presence of all claim limitations in the prior art was not obviated [by KSR]”, *Abbott Labs. v. Sandoz, Inc.*, 2007 WL 1549498, *4 (N.D. Ill. May 24, 2007)). Accordingly, Applicant respectfully request withdrawal of these rejections of Claims 38, 2-8, 10-13, and 16-22.

Even assuming *arguendo* that Carr is a proper reference under § 103 Carr does not render Claims 2-8, 10-13, 16-22 and 38 obvious. As discussed above, Carr does not disclose the features of Claim 38 explicitly or inherently. Carr does not disclose “adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein”. Carr also fails to disclose “mixing the hydrated protein solution with a concentrated fat to form a first food product” as recited in Claim 38. In making the alternative obviousness rejection, the Examiner does not indicate how Carr teaches these or other features of Claim 38. These are more than obvious variations of the disclosure of Carr. Carr discloses adding salt to milk followed by drying to form MPC with increased solubility in cold water. It does not teach addition of salt to a hydrated protein solution that is subsequently mixed with fat and does not provide any reason to enhance the ability of a hydrated protein solution comprising concentrated milk protein to emulsify fat in water or any suggestion to do so. Emulsification and solubility are not the same. There is no disclosure or reason to modify the process of Carr to improve emulsification properties and thus there is no reason to modify Carr and no teaching of how to do so.

Further, Carr teaches away from improving emulsification properties. As discussed above, any protein conformation maximizing solubility must fold the non-polar amino acids deep into the protein interior, essentially masking the inherent incompatibility of polar and non-polar compounds. Positioning the non-polar amino acids within the protein interior renders these sections incapable of simultaneously interacting with fat. Unable to interact with the fat, these proteins *cannot* effectively act as emulsifiers. Therefore, the disclosure of Carr regarding enhanced solubility teaches away from enhanced emulsification properties. Accordingly, Applicant requests withdrawal of this rejection for at least this reason.

Moreover, modifying the MPC of Carr to improve the emulsification properties would adversely affect the cold water solubility of the MPC because of the interaction of non-polar amino acid groups and water. This change would render Carr unsatisfactory for its intended purpose, to produce MPC with enhanced cold water *solubility*. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Accordingly, Applicant respectfully requests withdrawal of the rejection for at least this reason.

In addition, because modifying the MPC of Carr to improve the emulsification properties would adversely affect the cold water solubility of the MPC because of the interaction of non-polar amino acid groups and water, the modification proposed by the Examiner would change the principle of operation of Carr. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Accordingly, Applicant respectfully requests withdrawal of the rejection for at least this reason.

For the reasons discussed above, Applicant respectfully requests withdrawal of this rejection.

c. Claims 33-37 are patentable over the combined teachings of Carr and Sadowsky

Claims 33-37 stand rejected under 35 U.S.C. § 103 as unpatentable over Carr in view of U.S. Patent No. 6,358,551 to Sadowsky. Claim 33 is directed to a method for making cheese comprising homogenizing combined milk and fat to produce cream.

The Examiner found the claims to differ from Carr based on the recitation of specific cheese making steps. Office Action dated August 20, 2009 at page 3-4. The Examiner found Sadowsky to disclose “conventional cheese making steps including combining reconstituted skim milk with concentrated milk fat, homogenization, productions of a standardized milk, and use of the standardized milk to produce cheese (see entire patent, especially Figure 1). *Id.* at page 4.

Carr and Sadowsky fail to disclose a process to make cream. Claim 33 recites in part “homogenizing the combined milk and fat to produce cream”. Carr fails to disclose a process to make cream. For example, Example 9 of Carr discloses forming a milk solution containing 5.36% fat. Carr at page 12, line 18. Sadowsky also fails to disclose a method for making *cream*. Sadowsky discloses a method for incorporating concentrated milkfat into milk to form a slurry. Col. 5, ll. 30-50. Sadowsky discloses that “[g]enerally, the amount of concentrated milkfat added to the first portion of the reduced-fat raw milk is about 4 to about 10 percent.” Col. 5, ll. 43-45.

Example 1 of Sadowsky discloses forming a slurry with 8.4% fat. Example 2 of Sadowsky discloses forming a slurry with 3.9% fat. The slurries disclosed in Sadowsky are not cream. The skilled artisan will appreciate that cream has a much higher milk fat percentage. The slurries of Sadowsky do not contain enough milkfat to qualify as a cream under *any* of the FDA Standards of Identity promulgated in 21 C.F.R. § 131. For example, the FDA Standards of Identity state that heavy cream (21 C.F.R. § 131.150) contain not less than 36% milkfat, light cream (21 C.F.R. § 131.155) contain not less than 18% milkfat and not more than 30% milkfat, and light whipping cream (21 C.F.R. § 131.157) contain not less than 30% milkfat and not more than 36% milkfat.

Thus, Sadowsky also fails to disclose “homogenizing the combined milk and fat to produce cream” as recited in Claim 33. This is more than an obvious variation of Sadowsky. There is also no reason to modify Carr or Sadowsky to produce a cream because there are

different processing concerns for lower fat content materials, such as milk versus cream and higher fat materials.

For the reasons discussed above, the combination of Carr and Sadowsky fails to make Claim 33 obvious. Accordingly, Applicant respectfully requests withdrawal of the rejection of Claim 33. Additionally, Applicant submits that Claims 34-37, are not made obvious by Carr/Sadowsky, not only because they depend from Claim 33, but also on their own merit.

d. Carr and Sadowsky fail to render Claim 27 obvious

Applicant submits that Claim 27 is entitled to the priority date of the provisional application. Thus, as discussed above, Carr is not an appropriate prior art reference under 35 U.S.C § 103. Accordingly, Applicant requests withdrawal of Claim 27 for at least this reason.

Moreover, as Claim 17 depends from Claim 38, Applicants incorporate the arguments made above with respect to Claim 38. For example, as discussed above, Carr as modified by the Examiner does not disclose “adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein”. Sadowsky fails to make up for this deficiency and the other deficiencies of Carr discussed above. Accordingly, Applicant respectfully requests withdrawal of the rejection of Claim 27 for at least this reason.

e. Carr fails to anticipate Claims 39-45

The Examiner rejected Claims 39-45 under 35 U.S.C. § 102 as anticipated or in the alternative under 35 U.S.C. § 103 as unpatentable in view of Carr. Applicant notes that Claims 43-45 stand rejected as anticipated or made obvious by Carr. However, these claims depend from Claim 33, which stands rejected as unpatentable in view of Carr and Sadowsky. The Examiner failed to clarify this inconsistency despite Applicant’s request for clarification. Claims 43-45 will be treated as rejected by both Carr and the combination of Carr and Sadowsky. With regards to Claims 43-45, the Examiner found that “[t]he new claims are not seen to influence the conclusion of unpatentability previously set forth.” Office Action dated August 20, 2009 at page 3. Applicant respectfully disagrees.

Claims 39-42 depend from Claim 38. As discussed above, Carr fails to disclose all of the features of Claim 38, including, for example "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water" and "mixing the hydrated protein solution with a concentrated fat to form a first food product". Thus, Claims 39-42 are not anticipated or made obvious by Carr for at least this reason. No secondary references are cited and none of those cited by the Examiner make up for the deficiencies noted by Carr.

Claim 39 recites "wherein the first food product comprises high fat cream". Carr fails to disclose the production of any substances with greater than 5.36% fat. Example 9 of Carr discloses forming a milk solution containing 5.36% fat. The other examples of Carr fail to disclose any information regarding the fat content or the production of any substances with fat contents above those of Example 9. Thus, Carr fails to disclose a first food product comprising high fat cream. Accordingly, Applicant respectfully requests withdrawal of this rejection for at least this reason.

Claim 40 recites "wherein the high fat cream comprises 70% fat or greater", respectively. Carr fails to disclose the production of any substances with greater than 5.36% fat. Thus, Carr fails to disclose a high fat cream comprising 70% fat or greater.

Claim 41 recites "wherein the first food product comprises plastic cream" and Claim 42 recites "wherein the plastic cream comprises about 80% fat". Applicant notes that the F.D.A. does not have a specific standard of identity for plastic cream, however, 7 C.F.R. 58.305(e) defines plastic cream as sweet cream which has been pasteurized and contains approximately 80 percent milkfat. Carr fails to disclose the production of any substances with greater than 5.36% fat. Thus, Carr fails to disclose plastic cream as recited in Claims 41 and 42.

Claims 43-45 depend from Claim 33, which is rejected as unpatentable in view of the combination of Carr and Sadowsky. Therefore, according to the logic used by the Examiner Claims 43-45 cannot be anticipated by Carr alone. As noted above, the combination of Carr and Sadowsky fails to disclose or make obvious the features of Claim 33. Accordingly, Applicant respectfully requests withdrawal of the rejection of Claims 43-45 for at least this reason.

Claim 43 recites "wherein the cream comprises more than 36% fat". Carr fails to disclose the production of any substances with greater than 5.36% fat. Therefore, Carr fails to disclose a product with more than 36% fat. Thus, Carr fails to disclose the features of Claim 43.

Claim 44 recites "wherein the cream comprises high fat cream", respectively. Carr fails to disclose the production of any substances with greater than 5.36% fat. Therefore, Carr fails to disclose a product with more than 36% fat. Thus, Car fails to disclose the features of Claim 44.

Claim 45 recites "wherein the cream comprises plastic cream". Carr fails to disclose the production of any substances with greater than 5.36% fat. Therefore, Carr fails to disclose plastic cream. Thus, Car fails to disclose the features of Claim 45.

For the reasons discussed above, Applicant respectfully requests withdrawal of the rejection of Claims 39-45.

f. Claims 39-45 are not made obvious by Carr.

Applicant incorporates the arguments made above with respect to Claims 39-45. As discussed above, Carr fails to disclose the features of Claims 39-45.

Further, Claims 39-45 are not made obvious by Carr or Carr in combination with any secondary references. There is no reason in Carr, or any of the secondary references, to make a high fat product or any suggestion to do so. Further, there are different processing concerns for lower fat content materials, such as milk versus cream and higher fat materials. Accordingly, Applicant respectfully requests withdrawal of this rejection of Claims 39-45.

g. Claims 43-45 are not obvious in view of Carr and Sadowsky

Although Claims 43-45 are not actually rejected by the combination of Carr and Sadowsky. Applicant addresses Claims 43-45 as if they were rejected by Carr and Sadowsky in view of the inconsistency in the Examiner's rejection of these claims.

Claims 43-45 depend from Claim 33. As discussed above, Carr and Sadowsky fail to disclose the features Claims 43-45 recite "wherein the cream comprises more than 36% fat", "wherein the cream comprises high fat cream", and "wherein the cream comprises plastic cream", respectively.

Carr and Sadowsky also fail to teach these features. For example, Carr fails to disclose forming a first food product comprising high fat cream or plastic cream. Example 9 of Carr discloses forming a milk solution containing 5.36% fat. Carr at page 12, line 18. Sadowsky also fails to disclose this feature. For example, Examples 1 and 2 of Sadowsky disclose forming a

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slurry with 8.4% and 3.9% fat respectively. Further, Carr and Sadowsky are incapable of forming such a cream because the proteins lack the enhanced emulsification properties that allow formation of higher fat food products.

This is more than an obvious variation of Carr and Sadowsky. There are different processing concerns for forming a high fat product as recited in Claims 39-45, thus there would be no reasonable expectation of success for modifying Carr and Sadowsky to produce the recited food products. Accordingly, Applicant respectfully requests withdrawal of the rejection of these claims for at least this reason.

Dated: March 19, 2010

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VIII. CLAIMS APPENDIX

2. The method of Claim 38, further including adding an ingredient to the first food product in order to form a second food product.
3. The method of Claim 2, wherein the additional ingredient is milk.
4. The method of Claim 38, wherein the first food product is a dairy product.
5. The method of Claim 4, wherein the first food product is cream.
6. The method of Claim 5, wherein the cream is combined with milk to produce a second food product.
7. The method of Claim 6, wherein the second food product is used to make cheese.
8. The method of Claim 38, wherein the concentrated protein is a dehydrated protein.
10. The method of Claim 38, wherein the concentrated protein comprises casein.
11. The method of Claim 38, wherein the concentrated protein is nonfat dry milk.
12. The method of Claim 38, wherein the concentrated fat comprises milk fat.
13. The method of Claim 12, wherein the concentrated fat comprises about 95% milk fat.
16. The method of Claim 38, wherein the ionic composition of the hydrated protein solution is adjusted by changing the ionic composition of the hydration water prior to mixing with the protein.
17. The method of Claim 16, wherein the ionic composition of the water is adjusted by adding a monovalent salt to the water.
18. The method of Claim 17, wherein the monovalent salt is sodium chloride.
19. The method of Claim 17, wherein the monovalent salt is added to a concentration of about 0.25% to about 2.5%.
20. The method of Claim 38, wherein the ionic composition of the hydrated protein solution is adjusted by adding a monovalent salt to the solution after mixing with water.
21. The method of Claim 20, wherein the monovalent salt is sodium chloride.
22. The method of Claim 20, wherein the monovalent salt is added to a concentration of about 5 parts salt to about 15 parts salt per 100 parts protein.

27. The method of Claim 38, wherein the concentrated fat and hydrated protein are mixed in a high shear mixer or a high-pressure homogenizer.

33. A method of making cheese comprising:
mixing nonfat dry milk comprising milk proteins with water to form reconstituted skim milk, wherein the water comprises a monovalent salt prior to mixing;
combining the reconstituted skim milk with concentrated milk fat;
homogenizing the combined milk and fat to produce cream;
diluting the cream with milk to produce standardized milk; and
using the standardized milk to make cheese.

34. The method of Claim 33, wherein the water comprises from about 0.25 to about 2.5% of the monovalent salt.

35. The method of Claim 34, wherein the monovalent salt is sodium chloride.

36. The method of Claim 33, wherein the concentrated milk fat comprises about 95% anhydrous milk fat.

37. The method of Claim 36, wherein the concentrated milk fat comprises about 5% buttermilk powder.

38. A method of producing a food product from concentrated protein comprising:
mixing the concentrated protein with water to form a hydrated protein solution;
adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein, wherein the concentrated protein comprises concentrated milk protein; and
mixing the hydrated protein solution with a concentrated fat to form a first food product.

39. The method of Claim 38, wherein the first food product comprises high fat cream.

40. The method of Claim 39, wherein the high fat cream comprises 70% fat or greater.

41. The method of Claim 38, wherein the first food product comprises plastic cream.

42. The method of Claim 41, wherein the plastic cream comprises about 80% fat.

43. The method of Claim 33, wherein the cream comprises more than 36% fat.

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- 44. The method of Claim 33, wherein the cream comprises high fat cream.
- 45. The method of Claim 33, wherein the cream comprises plastic cream.

IX. EVIDENCE APPENDIX

The attached history of Fonterra Co-Operative Group LTD is attached, which can be found at
<http://www.fonterra.com/wps/wcm/connect/fonterracom/fonterra.com/our+business/fonterra+at+a+glance/about+us/our+history>

X. RELATED PROCEEDINGS APPENDIX

None

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